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FSSAI publishes FAQs on product approval

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FAIRS Subject Report

Approved By:
Allan Mustard
Prepared By:
Joshua Emmanuel Lagos and Radha Mani

Report Highlights:
This report reproduces a Food Safety and Standards Authority of India (FSSAI) fact sheet on the food product approval process. This information may help reduce confusion on process, especially on the necessity to apply for approval for domestic or imported products.

Executive Summary:

The Food Safety and Standards Authority of India (FSSAI) published a detailed fact sheet on the food product approval process. This initiative may help reduce confusion on process, especially on the necessity to apply for approval for domestic or imported products. Important highlights include information on (a) food products that have Codex or third country standards but no FSSAI standards; (b) organic products, ingredients, and additives; and (c) specific documentation to obtain product approval.

General Information:

DISCLAIMER: The information contained in this report was retrieved from the following Government of India website http://www.fssai.gov.in/. The U.S. Government makes no claim of accuracy or authenticity.

On October 14, 2014, FSSAI published a detailed fact sheet on the food product approval process. This initiative may help reduce confusion on process, especially on the necessity to apply for approval for domestic or imported products.
Important features include:

1. If Codex or other regulatory bodies have standards for the food product in question, the FBO needs to submit a product approval application attaching all relevant standards from these regulatory bodies. This may result in product approval or a referral to a scientific panel for further evaluation.

2. Organic products, ingredients, and additives are treated in the same manner as conventional products for product approval. In other words, there is no separate approval process for organics. Moreover, if a non-organic has already received product approval, its organic counterpart is also approved.

3. A specific, detailed list of documents needed to acquire product approval. This list helps reduce confusion about necessary documentation.

The full text of the document is given below and can also be accessed on the FSSAI website at:
http://www.fssai.gov.in/Portals/0/Pdf/PA_FAQ(14.10.14).pdf

FAQs ON PRODUCT APPROVAL

1. What is product approval?

   Product approval is the process by which a product gets approved by FSSAI in which the ingredient(s) and / or additive (s) are not as per prescribed standards in the act and regulations.

2. What is an No Objection Certificate (NOC)?

   A No Objection Certificate is an interim permission given to place a food product/ additives/ ingredients in the market.

3. Which food product(s) require Product Approval?

   Food Product(s) including food ingredient(s) or food additive(s) for which there are no standards notified by FSSAI will require product approval.

4. When does an FBO need to apply for product approval?

   An FBO needs to apply for product approval before licensing when the ingredient(s) and / or additive (s) used by him are those for which standards are not specified under FSS Act 2006, Rules and Regulations and are different from those of the products which are detailed in the FSS Act and Regulations.

5. What is the list of documents required for obtaining product Approval?

   The list of documents required for product Approval are as follows:

   a) Duly typed product approval application form in the prescribed format as uploaded on the website.
   b) Separate duly typed application form for each product with separate dossiers (in case of 'n' products)
   c) Differential amount for the products as per the advisory dated 11.05.2013.
   d) Certificate of analysis from National Accredited Board of Laboratories (NABL)
   e) Shelf life stability datasheet for the product.
   f) Copy of Notarized Affidavit on Rs.100 stamp paper (attached alongside).
   g) Copy of original label (in case if the product exist in the market)
   h) Copy of Prototype label (in case if the product is new and does not exist in the market)
   i) Detailed composition of the product with quantity of Ingredients and additives added in the product (as per serving size).
   j) Nutrient profile studies/risk assessment reports/toxicological studies/clinical trial reports of the products in human beings.
   k) The safety evaluation data on proposed product and ingredients regarding WHO, National/International agencies responsible for food safety or public health like Codex, USAFDA, EU, FSANZ etc.

l) Proof of import like IEC Certificate, Bill of Entry, Custom Invoice (in case of Import).
m) Copy of agreement between marketer and manufacturer (if any).
n) Copy of Previous Licence (if any).

Affidavit

I,Mr./Ms./Mrs.....S/o,D/o,W/o..... ..... of M/s..... .....(name and address of the company),..... by occupation (designation) and R/o.....is importing/manufacturing..... (name of ingredient/name of product) for last.....(No. of years) under (Name of Act/order) food license No..... (Copy enclosed).

That in my official capacity mentioned herein above and I am competent/authorized to swear this affidavit.

1. I further declare that the food business conducted or proposed to be conducted by/through

me /shall conform to the Food Safety and Standards Act 2006 Rules & Regulations made

there under.

2. I further declare that no court case against company is pending in any of the courts in the

country for contravention of the provision of the FSS 2006, Act,/ rules & regulations made

there under in respect of the product in question.

OR

(in the event of pending court cases, substitute this clause as under):

3. I/we further declare that there are pending cases against us for alleged contravention of

provision of the Food Safety Standard Act, 2006/ rules/regulations made thereunder details

of which are attached in the Annexure of the Affidavit. (Details/Disclosure of cases with case

numbers and name of the court to be furnished in the annexure).

4. I further declare that I company shall maintain the record of the traceability to facilitate the

recall operation of the food as per the requirement of the Food Safety and Standards Act,

2006 in case, the product is not approved by the FSSAI

Date:

Place:

Signature and seal

6. In case where the product is already approved under the product approval system, for minor compositional changes of ingredients e.g. Glucose is changed from 25% to 20%, 2% salt reduction, do a FBO need to apply for product approval again?.

Yes, except where FSS Regulations have been defined.

7. Does every product with even minimum change in composition or ingredient(s) and /or additive (s) require PA?

Yes, every product which has different ingredient(s) and / or additive (s) needs separate PA (except any number of flavours or colours can be accommodated in one application).

8. Is there a need for Product approval for products with same composition but different nomenclature e.g. aloo tikki vs.aloo patty, both having same/similar composition?

No, except in cases where different claim is made on the label.

9. What are traditional/ ethnic foods?

Traditional /Ethnic foods are foods which have been and are traditionally being consumed in the country

10. Whether traditional/ ethnic foods require product approval.

The traditional/ ethnic foods mentioned in the regulation 3.1.1. (2) of Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011 namely, - Snacks of Savouries (Fried Products), such as Chiwda, Bhujia, Dalmoth, Kadubale, Kharaboondi, Spiced and fried dals, banana chips and similar fried products sold by any name, Sweets, Carbohydrates based and Milk product based, such as Halwa, Mysore Pak, Boondi Ladoo, Jalebi, Khoya Burfi, Peda, Gulab Jamun, Rasogolla and similar milk product based sweets sold by any name, Instant Mixes Powders only of Idli mix, dosa mix, puliyogare mix, pongal mix, gulab jamoon mix, jalebi mix, vada mix, Rice and Pulses based Papads, Ready-to-Serve Beverages (tea/coffee based only) are not required to get product approval, provided it contains food additives permitted in Table 2 of Appendix A of Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011.

11. Whether organic food products need to apply for product approval?

Organic Food Products, ingredients and additives are treated in the same manner as non-organic products for the purpose of product approval. However, no separate product approval is required for the organic nature of the standardized product or which has otherwise been granted product approval.

12. Do Intermediary products which are not meant for consumer (for e.g. Premix) require product approval?

If the premix or intermediary products contain ingredients or additives which are not specified or do not have standards in the FSS regulation, these require product approval.

13. In case of vitamins and minerals, what are the permissible limits which can be added in the product?

As per ICMR guidelines, amount of vitamins and minerals as per RDA are permissible and all applications with these above RDA will be rejected.

14. In case botanicals are added what are the supplementary documents required to be submitted by the applicant?

All available literature and studies with respect to that botanical or product need to be submitted for examination in relation to safety of the product as food. Data of use, internationally for 30 years and nationally for 10 years is required for all ingredients which are not traditionally used.

15. What is meant by "plants or botanicals or substances from animal origin"?

This means that ingredients of plant or botanical and/or animal origin, which are not normally consumed as conventional foods or are not represented for use as conventional foods in India.

16. If I am manufacturing a food product, all ingredients of which are approved or allowed by FSS under its various regulations, but the product per se is not standardized, do I need to apply for approval?

Yes, it will be required.

17. Will the products mentioned in Annexure A or in any part of FSSR require approval?

No, they will not require PA.

18. In case the product contains ingredient(s) and / or additive (s) which are not mentioned in the Indian standard but their safety and usage limits are established by Codex and other regulatory bodies like EU/USFDA will PA be granted?

If safety of the product containing such ingredient(s) and / or additive (s) has been established by the above mentioned bodies then such products may be given PA.

19. If a FBO is adding new flavours or colours to the same product for which he already has approval from FSSAI, does he have to apply again for approval?

FBO needs to apply for PA only if the added colours or flavours are not approved in the FSSR.

20. If all ingredients are approved by FSSR but a new additive which is not allowed under FSSR is added, will I need an approval? If yes, which format should I apply in?

Yes. The application should be submitted in form 1(a) giving all relevant data on status of approval in Codex/USFDA/EU/ FSANZ etc. If it is not approved by any of these regulatory bodies, then it will be forwarded to Scientific Panel on Additives for evaluation.

21. In which category of the advisory will the age old ayurvedic ingredients fall? They are not permitted by FSSR but have been approved and authorised for use since ages. Will I need product approval for these ingredients?

Yes, if it is not normally consumed as conventional food and will fall under 1a category.

22. If an NOC has been granted on the basis of a product having different physical/chemical parameters (moisture, ash, pH etc) from those given in the standards for that product under FSSR, how wil the enforcement officer in the field know such details relevant for the grant of NOC? (as Physical/chemical parameters of a product are not mentioned in the NOC)

Such details will be mentioned in the NOC/ PA granted.

23. If an NOC has been granted for a certain product, is it mandatory for the FBO to carry out trading of that product with the exact same name as given in the NOC, or any other fancy name can be used on the product label, as long as the composition remains the same?

It will require product approval, e.g if flavored water is sold as herbal water, the name description changes.

24. If a proprietary ingredient (having NOC) is added to a standardized product, will the final product also become proprietary, and require product approval?

Yes.

25 When a company has sought product approval under Brand A and then wishes to manufacture the same product under a different Brand, would this require product approval again, with the formulation remaining same?

Yes, it is required. However, no additional fee needs to be paid.

26 In case one business entity (such as franchises etc.) of a company has obtained the product approval for Product X, will another business entity of the same company also required to file an application for product Approval for same Product X?

No, only the brand owner needs to obtain product approval.

27. Can the application for NOC/Product Approval be considered for any aspect of the product other than ingredient safety?

The PA Committee examines the ingredient safety and, if satisfied, grants a NOC or Approval, as the case may be. In case of issues like label declarations, claim, nutritional information etc., the Committee shall review the application with respect to the listing of ingredient(s); nutrient value of any new ingredient(s); claims related to new ingredient(s) for which approval is sought; and impact on food safety. However, FBO will be required to comply with the other relevant FSSAI Regulations for compliance. If necessary, the PA Committee may refer to the relevant Scientific Panel(s).

28. What are the Terms of Reference of the Product Approval (PA) Committee constituted under this advisory?

The PA Committee has the mandate to review the application in terms of the safety of the product or ingredient(s) and / or additive (s) for which the NOC/PA is sought by the applicant as mentioned in the advisory

29. How do I get to know if my application is complete or not? How will I be informed?

An attempt will be made to inform you by speed post within 10 working days from the date of receipt of your application.

30. Is it mandatory to pay an application fee for each product when it is referred to scientific panel?

No, any application seen in the screening committee meeting after 5th September, 2013 will be exempt from any additional fee for reference to scientific panel.

31. Will all applicants be awarded PA by FSSAI after they have applied?

No, only the applications of those products which are known to contain safe ingredient(s) and / or additive (s) as prescribed in the act and regulations will be granted PA. Other applications may be referred to scientific panel for recommendations with relation to safety of the ingredients

32. What is the status of the NOC, if the panel has rejected the application for the product approval

If the panel has refused to grant product approval for the food product food ingredient (s) or food additive (s) before or after the validity of NOC, the FBO should stop the manufacture/import/ place on the market that food product immediately and the license for the manufacturing of that food product and the NOC obtained from the FSSAI stands cancelled. In such case, the FBO should recall the product which is in the market, if any.

33. Whether food products for export purpose require product approval?

The product approval is required for the manufacturing of food products by 100% EOI units which sell and distribute a part of the food products domestically. Further, the units covered under the Special Economic Zones (SEZs) as defined by the Ministry of Commerce are not required to apply for the product approval.

34. Where should the FBO apply for FSSAI license after obtaining NOC/PA?

The FBO should get the license initially from the Central Licensing Authority for a period of one year after obtaining NOC. Once the product approval is issued, the same license will be shifted to the concerned state for state licensing, if it qualifies as per the eligibility criteria, else it would continued to be under central licensing.